Is Ahmed valve superior to Baerveldt implant as an aqueous shunt for the treatment of glaucoma?

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Abstract

Introduction

Aqueous shunt has emerged as an alternative technique to trabeculectomy, considered the standard for glaucoma surgery. Currently, it is mainly indicated after failure of trabeculectomy or in glaucoma with high risk of failure. The Ahmed valve and the Baerveldt implant are the most commonly used aqueous shunts. However, it is not clear whether there are differences between them.

Methods

To answer this question we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

Results and conclusions

We identified five systematic reviews including 10 studies overall, of which two were randomized trials. We concluded the Ahmed valve probably achieves a lower decrease in intraocular pressure, might lead to less qualified success and probably needs more reinterventions than the Baerveldt implant. Regarding safety profile, the Ahmed valve is not clearly superior or inferior to the Baerveldt implant.

Problem

According to the World Health Organization, glaucoma is the third cause of blindness worldwide[1]. Among the known risk factors for the development of this disease, the intraocular pressure is the only one that can be modified.

Since late 20th century, the introduction of aqueous shunts has emerged as an alternative surgery to trabeculectomy for patients with glaucoma and surgery indication. These devices are made up of a silicone tube with a lumen attached to an explant plate. The main indication of this technique is in those who, having an indication for surgical resolution, have failed to trabeculectomy or have subtypes of glaucoma in which this surgery has a high risk of failure. Currently, the most used techniques are the Ahmed valve and

the Baerveldt implant. They differ in that the Ahmed valve has a restricting flow mechanism for preventing postoperative hypotony. However, it is not clear which one is the best alternative.

Key messages

- The Ahmed valve probably achieves a lower decrease in intraocular pressure, might achieve less qualified success than the Baerveldt implant and probably increases the need for reoperation.
- The Ahmed valve might be equivalent to the Baerveldt implant in terms of changes in visual acuity.
- Regarding safety, the Ahmed valve might increase the development of choroidal effusion. However, it probably decreases the development of corneal edema, could decrease the development of narrow anterior chamber and it is not clear whether it increases the development of hypotonic maculopathy.

About the body of evidence for this question

What is the evidence. See evidence matrix in Epistemonikos later	We found five systematic reviews[2,3,4,5,6] including 10 primary studies reported in 16 references[7-22] of which two corresponded to randomized trials, reported in eight references[7,8,10,11,12,14-16]. This table and the summary in general are based on the randomized trials[10,14], since the observational studies did not increase the certainty of the evidence or provide additional relevant information.
What types of patients were included*	Regarding type of glaucoma, one trial included patients with primary open-angle glaucoma, primary chronic closed-angle glaucoma, neovascular glaucoma and uveitic glaucoma[10] and one trial included patients with primary open-angle glaucoma, primary chronic closed-angle glaucoma, neovascular glaucoma, uveitic glaucoma, post-traumatic glaucoma, combined mechanism glaucoma, congenital glaucoma and penetrating keratoplasty associated glaucoma[14]. Both trials included patients with patients glaucoma refractory to standard surgery or with a high risk of failure[10,14]
What types of interventions were included*	Both trials compared the Ahmed FP7 valve versus the Baerveldt 350 mm2 implant and placed them in the superotemporal quadrant[10,14] Regarding the use of antimetabolites, mitomycin C was not used in any of the arms of the trials[10,14]
What types of outcomes were measured	The trials measured multiple outcomes, which were grouped by the systematic reviews as follows: • Average intraocular pressure at the end of follow-up. • Percentage reduction of postsurgical intraocular pressure.

Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

	• Absolute reduction of postsurgical intraocular pressure. • Qualified success (achieving target intraocular pressure independent of the use of medical treatment). • Complete success (achieving target intraocular pressure without the need of medical treatment). • Complications (narrow anterior chamber, choroidal effusion, iritis, corneal edema, encapsulated bleb, tube obstruction, tube deviation, tube erosion, ocular motility alteration/ diplopia, hyphema, hypotonic maculopathy, endophthalmitis, corneal ulcer, dysesthesia, persistent diplopia, hypotony, malignant glaucoma, suprachoroidal hemorrhage, retinal detachment, cystic macular edema). • Need for reoperation. • Number of drugs used in the postoperative period. • Decrease in visual acuity. • Decrease in visual field. The average follow-up of the trials was 33 months, with a range between 12 and 60 months.

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of Findings

The information on the effects of the use of Ahmed valve compared to the use of Baerveldt implant is based on two randomized trials involving 514 eyes[10,14] .

Both trials reported mean intraocular pressure at the end of the follow-up (365 eyes) [10,14], qualified success rate (443 eyes), change of visual acuity (364 eyes), need of reintervention (514 eyes), corneal edema (514 eyes), risk of narrow anterior chamber (514 eyes) and risk of choroidal effusion (514 eyes). One trial evaluated hypotonic maculopathy (276 eyes)[10].

The summary of findings is the following:

- The use of Ahmed valve probably achieves a lower decrease in intraocular pressure compared to the use of Baerveldt implant. The certainty of the evidence is moderate.
- The use of Ahmed valve might achieve a lower qualified success than the use of the Baerveldt implant, but the certainty of the evidence is low.
- The use of Ahmed valve might be equivalent to the Baerveldt implant in terms of postoperative visual acuity change, but the certainty of the evidence is low.
- The use of Ahmed valve probably increases the need of reoperation compared to the use of the Baerveldt implant. The certainty of the evidence is moderate.
- The use of Ahmed valve probably decreases the development of corneal edema. The certainty of the evidence is moderate.
- The use of Ahmed valve might decrease the development of narrow anterior chamber, but the certainty of the evidence is low.
- The use of Ahmed valve might increase the development of the choroidal effusion, but the certainty of the evidence is low.
- It is not clear whether the use of Ahmed valve increases the development of hypotonic maculopathy, because de certainty of the evidence is very low.

Ahmed valve versus Baerveldt implant for glaucoma

Patients	Patients with glaucoma with indication of aqueous shunt
Intervention	Ahmed valve
Comparison	Baerveldt implant

Outcome	Absolute effect*		Relative effect (95% CI)	Certainty of evidence (GRADE)
	WITH Baerveldt implant	WITH Ahmed valve		
	Difference: patients per 1000			
Intraocular pressure (mmHg)	13.6 mmHg	15.3 mmHg	--	⨁⨁⨁◯ Moderate
	DM: 1.67 mm Hg more (Margin of error: 0.71 to 2.64 more)			
Qualified success	623 per 1000	535 per 1000	--	⨁⨁◯◯[1,2] Low
	Difference: 88 patients less (Margin of error: 162 less to 6 more)			
Visual acuity change (log-MAR)	1.52 units	1.52 units	--	⨁⨁◯◯[1,2] Low
	DM: 0 units (Margin of error: 0.26 less to 0.25 more)			
Reoperation	61 per 1000	138 per 1000	RR 2.28 (1.29 to 4.05)	⨁⨁⨁◯[1] Moderate
	Difference: 77 patients more (Margin of error: 17 to 185 more)			
Corneal edema	255 per 1000	166 per 1000	RR 0.65 (0.46 to 0.91)	⨁⨁⨁◯[1] Moderate
	Difference: 89 patients less (Margin of error: 23 to 138 less)			
Narrow anterior chamber	202 per 1000	184 per 1000	RR 0.91 (0.64 to 1. 29)	⨁⨁◯◯[1,2] Low
	Difference: 18 patients less Margin of error: 82 less to 59 more)			
Choroidal effusion	126 per 1000	142 per 1000	RR 1.13 (0.73 to 1.76)	⨁⨁◯◯[1,2] Low
	Difference: 16 patients more (Margin of error: 34 less to 95 more)			
Hypotonic maculopathy	30 per 1000	42 per 1000	RR 1.4 (0.4 to 4.84)	⨁◯◯◯[2,3] Very Low
	Difference: 12 patients more (Margin of error: 18 less to 116 more)			

Margin of error: 95% confidence interval (CI).
RR: Risk ratio.
MD: Mean difference.
GRADE: Evidence grades of the GRADE Working Group (see later).

*The risk WITH Baerveldt group is based on the risk in the control group of the trials. The risk WITH Ahmed group (and its margin of error) is calculated from relative effect (and its margin of error).

[1]One level of certainty of the evidence was downgraded due to a serious risk of bias in the included trials.
[2]One level of certainty of the evidence was downgraded due to imprecision of the results.
[3]Two levels of certainty of the evidence were downgraded due to a very serious risk of bias in the included trials.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

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* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision

Other considerations for decision-making

To whom this evidence does and does not apply

The evidence presented in this summary applies to glaucoma patients with surgical treatment indication, with failure or high risk of trabeculectomy failure, which is the main indication for the use of the aqueous shunt in glaucoma.

The patients included in the trials were adults. So, the results cannot be extrapolated to the pediatric population.

About the outcomes included in this summary

The outcomes included in this summary are those considered critical for decision-making by the authors of this summary. In general, they coincide with the outcomes most frequently reported by the identified systematic reviews.

The outcomes intraocular pressure reduction, qualified success and reoperation were chosen because they are crucial for the success of the procedure. In addition, complications of surgery were chosen as safety parameters of the intervention.

Balance between benefits and risks, and certainty of the evidence

The use of the Baerveldt implant probably achieves a greater decrease in intraocular pressure and a lower need for reoperation, and might achieve greater qualified success. In addition, it might decrease the development of choroidal effusion.

On the other hand, the use of the Ahmed valve probably decreases the development of corneal edema and might decrease the development of narrow anterior chamber. However, it is important to keep in mind the limitation of the existing evidence.

Even though the use of the Baerveldt implant seems to be more effective than the Ahmed valve, it is associated with an increase in complications. However, It is not possible to make an adequate balance between benefits and risks because of the existing uncertainty.

Resource considerations

None of the systematics reviews considered an economic analysis within its outcomes. Therefore, it is difficult to estimate if the cost-benefit would be favorable to the use of the Baerveldt implant, considering that it would be more effective, but it would increase some of the complications when compared to the use of the Ahmed valve.

If we consider the cost of each aqueous shunt, the Baerveldt implant is significantly less expensive than the Ahmed valve, thus attending to the conclusions of this work, it seems reasonable to consider the Baerveldt implant as more cost-effective.

What would patients and their doctors think about this intervention

Faced with the evidence presented in this summary, most clinicians should favor the use of the Baerveldt implant because it would achieve a greater decrease in intraocular pressure in the medium and long term.

However, the Ahmed valve unlike the Baerveldt implant, is technically easier to install and allows an immediate decrease in intraocular pressure, which is why its use could be preferred by clinicians, despite the favorable evidence for the latter.

The limited certainty of the evidence in some outcomes may also be a factor that leads to variations in decision-making, especially considering the larger clinical change perceived by patients is in visual acuity.

Differences between this summary and other sources

The systematic reviews reached similar conclusions to those presented here. However, the reviews were cautious about these results due to the limitations of the primary studies and their risk of bias.

The main guidelines recommend the use of aqueous shunts in patients who are refractory to standard surgery or at high risk of it[23,25] and in patients with moderate or advanced glaucoma as an alternative to trabeculectomy[24,25]. One clinical guideline concluded that the Baerveldt implant would have a higher efficacy but, considering its increase in complications, especially in those related to hypotony, it did not recommend one aqueous shunt over the other[25]. Other two guidelines did not report differences between both aqueous shunts.

Could this evidence change in the future?

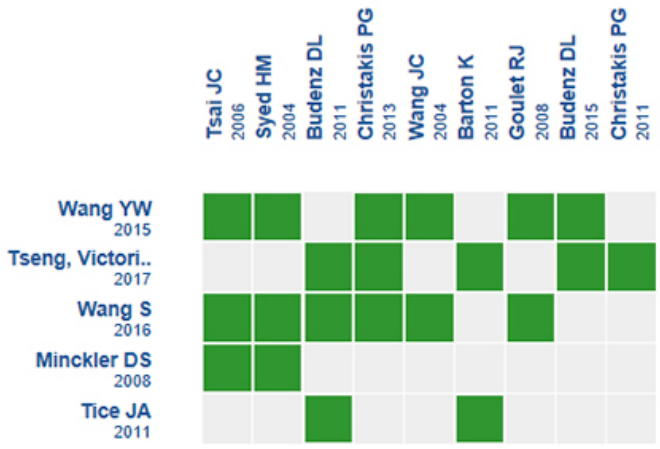
The probability that future research changes the conclusions of this summary is high, due to the uncertainty on the existing evidence.

No ongoing trials were found in the International Clinical Trials Registry Platform of the World Health Organization comparing the use of the Ahmed valve versus the Baerveldt implant.

We did not identify ongoing systematic reviews registered in the International Prospective Register of Systematic Reviews (PROSPERO) answering the question of interest.

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



An evidence matrix is a table that compares systematic reviews that answer the same question.
Rows represent systematic reviews, and columns show primary studies.
The boxes in green correspond to studies included in the respective revisions.
The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the **interactive version:** Ahmed valve versus Baerveldt implant for glaucoma

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (http://dx.doi.org/10.5867/medwave.2014.06.5997)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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